

of, records may be released only to authorized individuals, and the M+C organization must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released only in accordance with Federal or State laws, court orders, or subpoenas.

(b) Maintain the records and information in an accurate and timely manner.

(c) Ensure timely access by enrollees to the records and information that pertain to them.

(d) Abide by all Federal and State laws regarding confidentiality and disclosure for mental health records, medical records, other health information, and enrollee information.

**§ 422.128 Information on advance directives.**

(a) Each M+C organization must maintain written policies and procedures that meet the requirements for advance directives, as set forth in subpart I of part 489 of this chapter. For purposes of this part, *advance directive* has the meaning given the term in § 489.100 of this chapter.

(b) An M+C organization must maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care by or through the M+C organization.

(1) An M+C organization must provide written information to those individuals with respect to the following:

(i) Their rights under the law of the State in which the organization furnishes services (whether statutory or recognized by the courts of the State) to make decisions concerning their medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives. Providers may contract with other entities to furnish this information but remain legally responsible for ensuring that the requirements of this section are met. The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the State law.

(ii) The M+C organization's written policies respecting the implementation of those rights, including a clear and precise statement of limitation if the

M+C organization cannot implement an advance directive as a matter of conscience. At a minimum, this statement must do the following:

(A) Clarify any differences between institution-wide conscientious objections and those that may be raised by individual physicians.

(B) Identify the state legal authority permitting such objection.

(C) Describe the range of medical conditions or procedures affected by the conscience objection.

(D) Provide the information specified in paragraph (a)(1) of this section to each enrollee at the time of initial enrollment. If an enrollee is incapacitated at the time of initial enrollment and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, the M+C organization may give advance directive information to the enrollee's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated enrollee or to a surrogate or other concerned persons in accordance with State law. The M+C organization is not relieved of its obligation to provide this information to the enrollee once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to ensure that the information is given to the individual directly at the appropriate time.

(E) Document in a prominent part of the individual's current medical record whether or not the individual has executed an advance directive.

(F) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive.

(G) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives.

(H) Provide for education of staff concerning its policies and procedures on advance directives.

(I) Provide for community education regarding advance directives that may include material required in paragraph (a)(1)(i) of this section, either directly

or in concert with other providers or entities. Separate community education materials may be developed and used, at the discretion of the M+C organization. The same written materials are not required for all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable State law concerning advance directives. An M+C organization must be able to document its community education efforts.

(2) The M+C organization—

(i) Is not required to provide care that conflicts with an advance directive; and

(ii) Is not required to implement an advance directive if, as a matter of conscience, the M+C organization cannot implement an advance directive and State law allows any health care provider or any agent of the provider to conscientiously object.

(3) The M+C organization must inform individuals that complaints concerning noncompliance with the advance directive requirements may be filed with the State survey and certification agency.

#### § 422.132 Protection against liability and loss of benefits.

Enrollees of M+C organizations are entitled to the protections specified in § 422.502(g).

### Subpart D—Quality Assurance

SOURCE: 63 FR 35082, June 26, 1998, unless otherwise noted.

#### § 422.152 Quality assessment and performance improvement program.

(a) *General rule.* Each M+C organization that offers one or more M+C plans must have, for each of those plans, an ongoing quality assessment and performance improvement program that meets the applicable requirements of this section for the services it furnishes to its M+C enrollees.

(b) *Requirements for M+C coordinated care plans and network M+C MSA plans.* An organization offering an M+C co-

ordinated care plan or M+C network MSA plan must do the following:

(1) Meet the requirements in paragraph (c)(1) of this section concerning performance measurement and reporting. With respect to an M+C coordinated care plan, an organization must also meet the requirements of paragraph (c)(2) of this section concerning the achievement of minimum performance levels. The requirements of paragraph (c)(2) of this section do not apply with respect to an M+C MSA plan.

(2) Conduct performance improvement projects as described in paragraph (d) of this section. These projects must achieve, through ongoing measurement and intervention, demonstrable and sustained improvement in significant aspects of clinical care and nonclinical care areas that can be expected to have a favorable effect on health outcomes and enrollee satisfaction.

(3) In processing requests for initial or continued authorization of services, follow written policies and procedures that reflect current standards of medical practice.

(4) Have in effect mechanisms to detect both underutilization and overutilization of services.

(5) Make available to HCFA information on quality and outcomes measures that will enable beneficiaries to compare health coverage options and select among them, as provided in § 422.64(c)(10).

(c) *Performance measurement and reporting.* The organization offering the plan must do the following:

(1) Measure performance under the plan, using standard measures required by HCFA, and report its performance to HCFA. The standard measures may be specified in uniform data collection and reporting instruments required by HCFA, and will relate to—

(i) Clinical areas including effectiveness of care, enrollee perception of care, and use of services; and

(ii) Nonclinical areas including access to and availability of services, appeals and grievances, and organizational characteristics.

(2) Achieve any minimum performance levels that HCFA establishes locally, regionally, or nationally with respect to the standard measures.